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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,548

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EXAMINER

CHAN, CEDRIC A

ART UNIT

PAPER NUMBER

4151

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DELIVERY MODE

01/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/788,548	Applicant(s) GUSTAFSON ET AL.	
	Examiner Cedric Chan	Art Unit 4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,20 and 23-45 is/are pending in the application.
- 4a) Of the above claim(s) 38-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,20,23-38,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/08/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of invention I in the reply filed on December 06, 2007 is acknowledged. Claims 39-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim 38 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 06, 2007.

Drawings

2. The drawings are objected to because the reference numbers are hand-written and may be illegible in some instances. For instance, in Fig. 2, #18 may be incorrectly read as #10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 19, 23-28, and 44-45** are rejected under 35 U.S.C. 102(b) as being anticipated by Ogino (US 5,436,717).

Regarding claim 19, Ogino ('717) discloses an apparatus for analyzing particles comprising a flow cell (see Fig. 4 #16) that includes a passageway having an inlet (Col. 5, lines 23-24) and an outlet (Col. 5, line 27) that has a transparent wall (Col. 5, lines 22-23). '717 further teaches a conduit for delivering sample to the inlet of the flow cell and into the sample holding region, i.e., measurement passage (see Col. 5, lines 23-25), a light source (see Fig. 4 #10 & #18; see also Col. 5, lines 29-31), and a focused light path (Col. 5, line 62) positioned to direct light through the transparent wall into the sample to stimulate fluorescence. '717 also discloses a fluorescence analyzer, i.e. a photo detector, which in the case of a fluorescence-dyed slurry of particles, measures fluorescence intensity (see Fig. 4 #38, Col. 6 lines 13-14, and Col. 6, lines 15-17). It is noted that the article worked upon in the claimed apparatus does not impact patentability of an otherwise structurally identical apparatus. Patent '717, as discussed above, teaches all of the recited structural limitations of claim 19, and is therefore fully capable of functioning as claimed.

Regarding claim 23, '717 teaches a dichroic mirror (Fig. 8, #46) positioned proximate to a strobe light source (Fig. 8, #42) so as to allow light from said light source through to irradiate a flow cell (Fig. 8, #16). Another dichroic mirror (Fig. 8, #28) is positioned so as to direct light passing through the flow cell toward a photodetector (Fig. 8, #34). '717 further provides two photodetectors (Fig. 8, #34 & #38).

Regarding claim 24, the fluorescence analyzer taught by Ogino in '717 comprises the two photodetectors discussed previously, as well as a signal processor (Fig. 8, #52) for receiving and processing the signals from the photo detectors (see Col. 4, lines 40-44).

Regarding claim 25, the photo detector (Fig. 8, #34) is substantially orthogonal to the dichroic mirror (Fig. 8, #28).

Regarding claim 26, '717 teaches the provision of an objective lens (Fig. 8, #26) that is substantially perpendicular to the beam of light emitted from the strobe light source (Fig. 8, #42). Furthermore from Fig. 8, it is clear that the dichroic mirror (Fig. 8, #46) of '717 is positioned approximately 45-degrees with respect to the light beam and image path, and is located between the objective lens (#26) and another dichroic mirror (#30).

Regarding claims 27-28, the apparatus of '717 contains all of the structural elements required to be fully capable of performing the functions recited in claims 27-28.

Regarding claims 44-45, '717 teaches a flow cell, conduit, light source, signal processor, and fluorescence analyzer as previously discussed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogino (US 5,436,717) in view of Ogino et al. (US 5,428,441).

Ogino ('717) teaches all structural limitations recited in claim 19, as discussed above. However, '717 does not specifically disclose an optical system comprising a xenon strobe lamp.

Furthermore, the optical system taught by '717 does not include a filter, a mirror used to reflect light from the filter, and an objective lens between the mirror and the transparent wall.

Ogino et al. ('441) disclose an apparatus for analyzing particle images which utilizes a xenon strobe lamp as the light source (Col. 5, lines 56-57). Patent '441 also teaches an optical system which includes a filter that removes light outside of a desired range (see Fig. 1 #18; see also Col. 5, lines 63-66), a mirror used to reflect light from the filter toward the transparent wall of a flow cell (see Fig. 1 #20, Fig. 1 #24, and Col. 6, lines 2-7), and an objective lens between the mirror and the transparent wall for focusing the light on the sample in the flow cell (see Fig. 1 #22, and Col. 6, lines 14-15).

It would have been obvious to one of ordinary skill in the art to modify the light source taught in '717 with a xenon strobe lamp as taught in '441 in order to provide electromagnetic radiation at wavelengths appropriate for most fluorescent dyes (e.g., wavelengths ranging from ultraviolet to infrared). It would have been obvious to one of ordinary skill in the art to modify the optical system of '717 with the specific elements of '441 as discussed above, because doing so would increase the effectiveness of the excitation light, resulting in easier-to-detect fluorescence and increased accuracy of analysis results.

9. **Claims 29-31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogino (US 5,436,717) in view of Cubbage et al. (US 5,582,982) and Ferrari (US 3,065,148).

Ogino ('717) teach the components of the apparatus recited in claim 19, as discussed above. However, '717 does not specifically disclose a means to control the amount of stain in solution.

Cubbage et al. teaches the use of specific compounds to reduce background fluorescence in biological assays involving fluorescently stained biological components (see Abstract).

Ferrari teaches an apparatus for use in conducting studies on cells, comprising a proportioning pump which operates to pump two different types of solution, the two different types of solution being held in fluid receptacles (see Col. 2, lines 22-26 & 32-33). The pump transmits the mixed solution through tubular conduits (see Col. 2, line 27-28) and ultimately into a flow cell (see Col. 4, lines 40-42).

It would have been obvious to use a background reducing, i.e. bleaching, compound as taught by Cubbage et al. in order to enhance contrast between fluorescence-stained fibers and the background solution, which in turn would enhance the accuracy of the analytical device of Ogino ('717).

It would have been obvious to employ the fluid transport system taught by Ferrari in the particle analyzer of Ogino ('717) because the proportional pumping system would allow for the release of a pre-determined proportion of sample and bleaching solution, so that the correct amount of bleach is released every time (reducing the risk of over-bleaching of the sample solution).

10. **Claims 32-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogino (US 5,436,717) in view of Holm et al. (US 4,172,524).

Regarding claims 32-34, Ogino ('717) teaches the structural limitations recited in claim 19, as previously discussed. However, '717 does not specifically disclose an automated synchronized imaging system.

Holm et al. teaches an inspection system for detecting excessive particulate matter comprising multiple cameras, and synchronization means. Horizontal and vertical sync lines synchronize the operation of the imaging system (see col. 15, lines 37-44).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the synchronized imaging system as taught by Holm et al. with the particle analyzing apparatus of '717, because synchronization of the images allows for the analytical comparison of the same sample.

Regarding claims 35-37, the apparatus of '717 contains all of the structural elements recited in claim 33 as discussed above, and thus it is held that the combination of Ogino/Holm is fully capable of performing the functions recited in claims 35-37.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cedric A. Chan whose telephone number is (571)270-3721. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Kornakov can be reached on (571) 272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4151

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.C./

16 January 2008

/Michael Kornakov/

Supervisory Patent Examiner, Art Unit 4151